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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,735

09/29/2006

Valerie Andre

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1588

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EXAMINER

FRAZIER, BARBARA S

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/594,735	<b>Applicant(s)</b> ANDRE ET AL.	
	<b>Examiner</b> BARBARA FRAZIER	<b>Art Unit</b> 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 3-11 and 13-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/25/09 has been entered.

### ***Status of Claims***

2. Claims 1-20 are pending in this application.
3. Claims 3-11 and 13-20 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/24/08.
4. Claims 1, 2, and 12 are examined.

### ***Claim Rejections - 35 USC § 103***

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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**6. Claims 1, 2, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanner et al (US Patent 5,827,508) in view of Meguro et al (US Patent 4,640,943) and Mazo et al (US Patent 5,939,518).**

The claimed invention is drawn to a surface-modified nanoparticulate metal oxide, wherein the surface modification comprises a coating with polyasparaginic acid with a molecular weight  $M_w$  of from 1000 to 7000, and the metal oxide particles have an average primary particle diameter of from 10 to 200 nm (see claim 1).

Tanner et al teach compositions having enhanced stability that are useful for protecting human skin from the harmful effects of UV radiation, comprising a surface-treated zinc oxide (see col. 2, lines 48-56). The surface-treated zinc oxides have a mean particle size preferably from about 0.01 to about 10 microns (i.e., from about 10 to about 10,000 nm), and more preferably from about 0.01 to about 2 microns (i.e., from about 10 to about 2,000 nm) (see col. 6, lines 36-42). This particle size range encompasses that of the claimed invention; one skilled in the art would be motivated to select particle size from within said ranges by routine experimentation, in order to optimize properties of the resultant particle, such as stability and flowability. The surface treatment materials useful for treating the zinc oxide particles include amino acids (col. 6, lines 65-67).

Tanner et al do not specifically teach that the amino acid is polyasparaginic acid.

Meguro et al teach that surface modifiers such as polyaspartic acid are known in the art to be used for the purpose of improving the wettability and enhancing the dispersibility of inorganic fillers such as oxides of titanium, zinc, and iron (see col. 2,

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lines 3-6 and 17, and col. 1, lines 13-18). The metal oxides may be used in cosmetic formulations (col. 1, lines 37-39).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to select the polyaspartic acid surface modifier taught by Meguro et al as the amino acid surface treatment material of Tanner et al, thus arriving at the claimed invention. One skilled in the art would have been motivated to do so because the use of polyaspartic acid as the amino acid surface modifier provides the benefits of improving the wettability and enhancing the dispersibility of the metal oxide, as taught by Meguro et al. One would reasonably expect success from the use of polyaspartic acid taught by Meguro et al with the metal oxides taught by Tanner et al because both references are drawn to the use of surface-treated metal oxides in cosmetic formulations.

Meguro et al is silent with respect to the specific molecular weight of the polyaspartic acid.

However, Mazo et al teach that polyaspartates are becoming increasingly useful as additives for cosmetics and personal care products (col. 1, lines 14-17), and having "desired high molecular weight" (col. 1, lines 41-42). The polyaspartates are prepared by hydrolyzing polysuccinimides (col. 3, lines 8-10), which have a weight average molecular weight ( $M_w$ ) in the range of about 3,000 to about 40,000 (col. 3, lines 39-41). Therefore, the  $M_w$  of the polyaspartates would be comparable to that of the polysuccinimides (i.e., about 3,000 to about 40,000).

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It would have been obvious to a person having ordinary skill in the art at the time the invention was made to select the molecular weight of the polyaspartic acids taught in Mazo et al for the polyaspartic acid surface modifiers of Mazo et al. One skilled in the art would have been motivated to do so because high molecular weights of polyaspartic acid are desired as dispersants and additives for cosmetics and personal care products, as taught by Mazo et al. Additionally, the molecular weight range taught by Mazo et al overlaps that of the claimed invention; one skilled in the art would be motivated to select molecular weight of polyaspartic acid from within said ranges by routine experimentation, in order to optimize properties of the polyaspartic acid, such as dispersibility. A skilled artisan would reasonably expect success from the selection of the polyaspartic acids of Mazo et al for the polyaspartic acid surface modifiers of Meguro et al because both compositions are drawn to using polyaspartic acid in cosmetics and personal care products.

With respect to claim 2, Tanner et al teach a surface-treated zinc oxide (col. 2, lines 55-56).

With respect to claim 12, Tanner et al teach that the compositions of the present invention are useful for providing protection to human skin from the harmful effects of UV radiation (col. 15, lines 34-36), and may include other cosmetic ingredients (col. 14, lines 54-62).

***Response to Arguments***

7. Applicant's arguments filed 6/25/09 have been fully considered but they are not persuasive.

Applicants argue that, in response to the Office Action's statement at page 6, lines 16-20, that using the polyasparaginic acid to decrease the particle size of the metal oxide particles is not recited in the pending claims, that the method claims have been previously withdrawn, and the pending product claims recite a molecular weight that allows precipitating metal oxide particles with the recited particle size range.

This argument is not persuasive because the particle size range and molecular weight range of the claimed invention overlap those of the invention of the combined references, as delineated above, and one skilled in the art would be motivated to select particle size and weight of the polyasparaginic acid from within said ranges by routine experimentation, in order to optimize properties of the polyaspartic acid, such as dispersibility.

Applicants argue that the Office action relies on Tanner for a suggestion of a zinc oxide particle size of from about 10 to 10,000 nm, i.e., three orders of magnitude, and that, at page 7, lines 7-10, the Office Action asserts that a skilled artisan would expect that a high molecular weight polyaspartic acid results in an increased particle size.

Applicants then pose two questions:

“Does this also mean a skilled artisan would expect that a low molecular weight results in coated particles having a small particle size? Further, would a skilled artisan expect that using aspartic acid, i.e., the compound actually suggested in Tanner, result in a coating of elemental silicon atoms?”

In response to Applicant's comment regarding Tanner, it is noted that Tanner actually teaches a preferred particle size range of from about 10 to about 2,000 nm, which overlaps the range of the claimed invention. In response to Applicant's comment regarding page 7, lines 7-10 of the Office Action, it is noted that page **10**, lines 7-10, of the Office Action states that one skilled in the art would reasonably expect polyaspartic acid of higher molecular weight (g/mol) to result in particles of increased particle size, that is to say, that as the molecular weight of polyaspartic acid increases, the size of the particle coated with said polyaspartic acid would be expected to increase as well, all other factors (such as density and core material) being equal. In response to Applicant's two questions, it is not clear what Applicants are arguing here. If Applicants are arguing the relationship between molecular weight and particle size, it is the Examiner's position that a compound of higher molecular weight will occupy a greater area, due to the scientific principle that mass is directly proportional to volume. Therefore, absent evidence to the contrary, as the molecular weight of polyaspartic acid increases, the size of the particle coated with said polyaspartic acid would be expected to increase as well, all other factors (such as density and core material) being equal.

Applicants argue that, as set forth in the Declaration under 37 CFR 1.132 (it is noted that the Declaration was filed under 37 CFR 1.131; see paragraph 10, below), it was not known to the inventors that using the preferred molecular weight of from 1000 to 7000 g/mol would result in the preferred particle before conducting the actual experiment, and it was also not known that precipitating metal oxide particles in the



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presence of polyasparaginic acid would influence the particle size of the precipitated coated particles.

The data in Applicant's specification has been fully considered, but is not persuasive for overcoming the rejection. The declaration has not been submitted under the proper Rule (37 CFR 1.132), and therefore is not a proper Declaration. Additionally, Applicant's results are not unexpected, as a zinc oxide particle coated with a polyaspartic acid of higher molecular weight would be expected to be a larger particle size than a zinc oxide particle coated with a polyaspartic acid of lower molecular weight, all other factors (such as density and core material) being equal. In response to Applicant's argument that it was not known that precipitating metal oxide particles in the presence of polyasparaginic acid would influence the particle size of the precipitated coated particles, it is noted that the claims are drawn to a product, and do not include the process steps of precipitating metal oxide particles in the presence of polyasparaginic acid.

In response to Applicant's argument that the average particle size decreases slightly from 172 to 170 nm by using polyasparaginic acid having a molecular weight of 5,800 instead of 4,000, it is noted that a difference from 172 to 170 nm, or about 1%, is not statistically significant, and does not demonstrate unexpected results, particularly in light of the fact that the rest of the data shows a trend of increasing particle size with increasing molecular weight (page 3 of the Declaration).

Therefore, it is the Examiner's position that the claims are rendered obvious.

**8. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kropf et al (US 2004/0033270) in view of Mazo et al (US Patent 5,939,518).**

The claimed invention is delineated above (see paragraph 5).

Kropf et al teach hygiene products produced using zinc oxide in the form of nanoparticles having surfaces that have been modified using organic compounds such as amino acids (abstracts). The particularly preferred average primary particles size of the zinc oxide nanoparticles is 5 to 20 nm, 10-25 nm or 15-35 nm (paragraph 14). The surface modifier may be polyaspartic acid (paragraph 48).

Kropf et al is silent with respect to the specific molecular weight of the polyaspartic acid.

However, Mazo et al teach that polyaspartates are becoming increasingly useful as additives for cosmetics and personal care products (col. 1, lines 14-17), and having “desired high molecular weight” (col. 1, lines 41-42). The polyaspartates are prepared by hydrolyzing polysuccinimides (col. 3, lines 8-10), which have a weight average molecular weight ( $M_w$ ) in the range of about 3,000 to about 40,000 (col. 3, lines 39-41). Therefore, the  $M_w$  of the polyaspartates would be comparable to that of the polysuccinimides.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to select the molecular weight of the polyaspartic acids taught in Mazo et al for the polyaspartic acid surface modifiers of Kropf et al. One skilled in the art would have been motivated to do so because high molecular weights of polyaspartic acid are desired as dispersants and additives for cosmetics and personal care products,

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as taught by Mazo et al. Additionally, the molecular weight range taught by Mazo et al overlaps that of the claimed invention; one skilled in the art would be motivated to select molecular weight of polyaspartic acid from within said ranges by routine experimentation, in order to optimize properties of the polyaspartic acid, such as dispersibility. A skilled artisan would reasonably expect success from the selection of the high molecular weight polyaspartic acids of Mazo et al for the polyaspartic acid surface modifiers of Kropf et al because both compositions are drawn to using polyaspartic acid in cosmetics and personal care products.

Regarding claim 2, Kropf et al teach surface modified zinc oxide (see abstract).

### ***Response to Arguments***

9. Applicant's arguments filed 6/25/09 have been fully considered but they are not persuasive.

Applicants argue that the application of Mazo fails for the same reasons set forth above [in the rejection of Tanner in view of Meguro and Mazo].

Since the above arguments are not persuasive for reasons set forth above (see paragraph 7), and Applicants have not further argued the merits of Kropf or Mazo, the rejection is maintained for reasons of record.

### ***Response to Declaration***

10. The declaration filed on 6/25/09 under 37 CFR 1.131 has been considered but is ineffective to overcome the references of Tanner, Meguro, Mazo, and Kropf.

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11. The Tanner reference, as well as the Meguro and Mazo references, are a statutory bar under 35 U.S.C. 102(b) and thus cannot be overcome by an affidavit or declaration under 37 CFR 1.131.

12. The evidence submitted is insufficient to establish a reduction to practice of the invention in this country or a NAFTA or WTO member country prior to the effective date of the Kropf reference. Applicants have not provided any evidence in this 131 Declaration with regards to antedating, or swearing behind, the Kropf reference.

13. The Examiner notes that, while the Declaration is submitted under 37 CFR 1.131 (see page 1 of Declaration), it appears that the subject matter of the Declaration is directed to traversing the outstanding rejections, and would more appropriately be submitted as a Declaration under 37 CFR 1.132. It is further noted that Applicant refers to said Declaration as "the enclosed Declaration under 37 CFR 1.132", even though the Declaration itself is labeled as "Declaration Under 37 CFR 1.131".

### ***Conclusion***

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BARBARA FRAZIER whose telephone number is (571)270-3496. The examiner can normally be reached on Monday-Thursday 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571)272-0614. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BSF

/Sharmila Gollamudi Landau/  
Supervisory Patent Examiner, Art Unit 1611